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| 10/010,706 | 12/04/2001 | Kanwaljit Singh Girm | FGX-100US | 7051 |
| 23122 | 7590 | 06/29/2005 | EXAMINER | |
| RATNERPRESTIA P O BOX 980 VALLEY FORGE, PA 19482-0980 | | | LY, CHEYNE D | |
| | | | ART UNIT | PAPER NUMBER |
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DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,706

Applicant(s)

GIRN ET AL.

Examiner

Cheyne D. Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 12-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8 and 11 is/are rejected.
- 7) ☒ Claim(s) 3,9 and 10 is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' arguments filed March 16, 2005 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The new title has been accepted.
3. The withdrawal of claims 12-25 has been acknowledged.
4. Claims 1-11 are examined on the merits.
5. NON-FINAL OFFICE ACTION.

OBJECTIONS

6. Claims 3, 9, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112, Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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9. Claim 5, lines 3-4, recites the limitation of “to the exclusion of the data gathering and evaluation system” which cause said claim to be vague and indefinite. For example, the new limitation could reasonably be construed as the claimed method no longer requires “the data gathering and evaluation system” or the “storing any information” is information not present in said system. Clarification of the metes and bounds of the claim is required.

Claim Rejections - 35 USC § 112, First Paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. NEW MATTER REJECTION.

12. Claim 5, lines 3-4, recites the limitation of “to the exclusion of the data gathering and evaluation system” which has not been found in the instant specification.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1, 4, 8, and 11 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Westman et al. (May 2000).

15. Westman et al. describes a computer-aided method for cancer risk assessment comprising a freestanding computer system (first) collecting family history information via a touch-screen (Abstract etc.). The individual selects a cancer type from the twenty-seven types of cancer available in Table 1 (page 356, lines 24-51). The information from the individual is stored in a database (second) via the hospital local area network (page 355, column 2, lines 5-10). After the selection, the individual is prompted for family history data in a communications loop wherein the individual is provided with an explanation directed to metastatic cancers risk assessments (page 356, lines 24-51, and Figure 7), which represents the direct communication of cancer susceptibility to the individual via the first computer as claimed in the last 2 lines of instant claim 1. Further, the computer system (first) utilized by the individual includes Internet Explorer 5.0 wherein "much of the touchscreen technology incorporates significant portions of the Explorer browser for its functionality" (page 355, column 2, lines 5-13) wherein the browser represents the reporting feature available via the Explorer browser. For example, Figure 7 (page 357) reports in the first computer system via the Internet Explorer 5.0 "A spread site (metastasis) is a growth that started from the original cancer. Therefore, a spread site would be counted as a 'new' cancer", which represents susceptibility, as in instant claim 1.

16. The freestanding computer system (first) is connected to a database (second) via the hospital local area network via a secure network (page 355, column 2, lines 5-10), as in instant claim 4.

17. Table 2 describes the distribution of risk as directed to the individuals (page 358) wherein the percentage of risk has been reasonably construed as a type of statistical risk, as in instant claim 8.

18. Westman et al. describes a computer-aided method for cancer risk assessment comprising a freestanding computer system (first) collecting family history information via a touch-screen (prompts) (Abstract etc.). The individual selects a cancer type from the twenty-seven genetically linked cancer types available in Table 1 (page 356, lines 24-51, and page 357). The information is stored in a database (second) via the hospital local area network (page 355, column 2, lines 5-10). After the selection, the individual is prompted by the touch-screen (receiving and displaying) to provide information directed to family history as directed to cancer. The family history data and selected cancer data are prompted in an interactive loop with decision points directed to family history information which represents the modifying of family history. The individual is provided with an explanation directed to metastatic cancers risk assessments (page 356, lines 24-51, and Figure 7), which represents the communication of cancer susceptibility to the individual. These risk assessment criteria are used to identify patients at increased risk for cancer based upon their family history (page 356, lines 52-48). Further, the computer system (first) utilized by the individual includes

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Internet Explorer 5.0 wherein “much of the touchscreen technology incorporates significant portions of the Explorer browser for its functionality” (page 355, column 2, lines 5-13) wherein the browser represents the reporting feature available via the Explorer. For example, Figure 7 (page 357) reports in the first computer system via the Internet Explorer 5.0 “A spread site (metastasis) is a growth that started from the original cancer. Therefore, a spread site would be counted as a ‘new’ cancer”, which represents susceptibility, as in instant claim 11.

CLAIM REJECTIONS - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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21. Claims 1, 2, 4, 6-8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westman et al. (May 2000).

22. Westman et al. describes the limitations to claims 1, 4, 8, and 11 as cited above.

23. Westman et al. does not explicitly describe the reporting to include the limitations required by claims 2, 6, and 7.

24. Individuals categorized as high risk receive a recommendation to have genetic counseling (page 356, last paragraph), as in instant claim 2.

25. The report contains data tailored to the individual wherein the data comprises name, cancer found in family and relatedness of affected family members (summary) (page 357, lines 21-30), as in instant claims 6 and 7.

26. Westman et al. further describes computer programming is now required for the automation of the risk assessment portion of the process to allow for the immediate receipt of risk assessment feedback information (page 359, column 2, lines 35-49). Further, the first computer system of Westman et al. comprising the Internet Explorer browser (reporting) connected to the second computer system via a LAN wherein data is transmitted between the first computer system and the second computer system (page 355, column 2, lines 5-10). Westman et al. suggests a reasonable expectation of success for the automation of risk assessment because Westman et al. via page 359, as cited above, describes the “combination

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of computer technology, knowledgeable genetic professionals, and tailored risk assessment communication has been shown to be efficient, feasible, and effective..." which motivates and suggests that only programming is yet needed for said automation. As cited above, Westman et al. suggests a reasonable expectation of success for reporting via the HTML based Internet Explorer browser. For example, Tittel et al. supports via the book, HTML for Dummies, programming via HTML for reporting in Internet Explorer can be accomplished even by beginners (pages 1-2). Therefore, An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the described improvement of providing "efficient, feasible, and effective" immediate risk assessment information to provide immediate reporting to the first computer system via the Internet Explorer browser. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the computer-aided method for cancer risk assessment with immediate reporting via the Internet Explorer browser to the first computer system as instantly claimed.

CONCLUSION

27. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

28. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent

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number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

29. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly
6/26/05


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER